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GENFIT: Positive 42-month DSMB Recommendation for Continuation of Phase 3 RESOLVE-IT Study of Elafibranor in NASH

- **Data Safety Monitoring Board (DSMB) recommends the continuation of the RESOLVE-IT clinical trial without any modifications, based on the pre-planned review of safety data**
- **DSMB guidance remains consistent, supporting favorable safety profile of elafibranor**

Lille (France), Cambridge (Massachusetts, United States), November 26, 2019 – **GENFIT (Euronext: GNFT – Nasdaq: GNFT)** a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases, today announced that the Data Safety Monitoring Board (DSMB) issued a positive recommendation for the continuation, without any modifications, of the RESOLVE-IT Phase 3 trial evaluating elafibranor in NASH.

The 42-month DSMB safety review supports GENFIT's continuation of the RESOLVE-IT study. This DSMB recommendation marks the seventh review with no safety signals that would justify modification or discontinuation of the study, including review of safety data from patients in the study who have received elafibranor for as long as three years.

Drugs such as elafibranor, a PPAR α/δ agonist, and seladelpar, a PPAR δ agonist, target nuclear receptors, which can exhibit variability in terms of safety, potency, and efficacy. In trials with elafibranor to date, there have been no issues with interface hepatitis. Elafibranor has achieved about 2000 collective years of human exposure across its clinical development program in Phases 1-3, and DSMB reviews of elafibranor safety and tolerability data have supported continuation of the ongoing Phase 3 RESOLVE-IT study without any modification.

This most recent DSMB recommendation supports that elafibranor is generally safe and well tolerated in completed and ongoing clinical studies, which is critical for drug candidates that are aimed to treat chronic diseases such as NASH or PBC. Top-line interim results from the Phase 3, RESOLVE-IT trial, based on the primary endpoint of NASH resolution without worsening of fibrosis, are expected to be announced in Q1 2020. If positive, GENFIT aims to file a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) by the end of 2020. Elafibranor has received fast track designation from the FDA for the treatment of NASH. If approved, elafibranor could be the first approved therapy for resolution of NASH without worsening of fibrosis.

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"*This seventh, favorable DSMB review is further confirmation that our RESOLVE-IT trial can continue without modification, keeping us on track for an NDA filing by the end of 2020. It strengthens our confidence that elafibranor is generally safe and well tolerated, which is paramount for drugs that are intended to treat a chronic and silent disease such as NASH. We hold great hope for elafibranor based upon safety and efficacy data in the GOLDEN-505 study and based upon available safety data from the ongoing Phase 3 RESOLVE-IT trial,* commented Dr. Carol Addy, Chief Medical Officer at GENFIT. *Taken together, this is supportive of continuing with our Phase 3 RESOLVE-IT trial in NASH, initiating our combination program in NASH to evaluate elafibranor when administered with an SGLT2 inhibitor or a GLP-1 receptor agonist, as well as the continuation of our therapeutic program in primary biliary cholangitis (PBC).*"

ABOUT RESOLVE-IT

RESOLVE-IT is a phase 3 study evaluating the efficacy and safety of elafibranor 120mg versus placebo in patients with nonalcoholic steatohepatitis (NASH) and fibrosis. It is a multicenter, randomized, double-blind, placebo-controlled study with 2 arms. It is conducted under Subpart H (FDA) and conditional approval (EMA). Treatment duration until interim analysis for accelerated approval is 72 weeks.

ABOUT ELAFIBRANOR

Elafibranor, GENFIT's lead pipeline therapeutic candidate, has been developed to treat, in particular, nonalcoholic steatohepatitis (NASH), for which it has been granted Fast Track Designation by FDA. Elafibranor is an oral, once-daily, first-in-class drug acting via dual agonism of peroxisome proliferator-activated alpha/delta receptors GENFIT believes, based on clinical results to date, that elafibranor has the potential to address multiple facets of NASH, including liver inflammation/injury, insulin sensitivity, and lipid/metabolic parameters. Phase 2 clinical trial results have also shown that elafibranor may be an effective treatment for PBC, a chronic liver disease. Elafibranor was granted a Breakthrough Therapy Designation by FDA in this indication.

ABOUT NASH

NASH is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. The disease is associated with an increased risk of cardiovascular disease along with long-term risk for progression to cirrhosis, leading to liver insufficiency and potential progression to liver cancer. NASH is a serious disease that often carries no symptoms in its early stages, but if left untreated can result in cirrhosis, cancer, and the need for liver transplant. The prevalence of NASH is rapidly increasing as a result of the

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growing obesity and diabetes epidemics and is believed to affect as much as 12 percent of people in the U.S. and six percent worldwide.

ABOUT PBC

Primary biliary cholangitis (PBC) is a chronic, autoimmune disease in which bile ducts in the liver are gradually destroyed. The damage to bile ducts can inhibit the liver's ability to rid the body of toxins, and can lead to scarring of liver tissue, known as cirrhosis. Elafibranor has shown promising results for the treatment of PBC in a Phase 2 clinical trial, and was granted the Breakthrough Therapy Designation by the FDA in this indication.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to the discovery and development of innovative therapeutic and diagnostic solutions in metabolic and liver related diseases where there are considerable unmet medical needs, corresponding to a lack of approved treatments. GENFIT is a leader in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning almost two decades. Its most advanced drug candidate, elafibranor, is currently being evaluated in a pivotal Phase 3 clinical trial ("RESOLVE-IT") as a potential treatment for NASH, and GENFIT plans to initiate a Phase 3 clinical trial of elafibranor in PBC in 2020, following its positive Phase 2 results. As part of GENFIT's comprehensive approach to clinical management of patients with NASH, the company is also developing a new, non-invasive blood-based diagnostic test, NIS4, which, if approved, could enable easier identification of patients with NASH. With facilities in Lille and Paris, France, and Cambridge, MA, USA, the Company has approximately 200 employees. GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and in compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). www.genfit.com

FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to GENFIT, including the potential of elafibranor to treat NASH and PBC, elafibranor's continued efficacy and safety profile, expectations regarding the timing of release of top-line results from the Phase 3 RESOLVE-IT trial and of filing of new drug applications with regulatory authorities, the potential of elafibranor to be the first approved therapy for resolution of NASH without worsening of fibrosis and the continuation of GENFIT's other therapeutic programs.TThe use of certain words, including "believe," "potential," "expect" and "will" and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the

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current expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and unknown risks and uncertainties, which could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, among other things, the uncertainties inherent in research and development, including related to safety, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates and the Company's continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the French Autorité des marchés financiers ("AMF"), including those listed in Section 4 "Main Risks and Uncertainties" of the Company's 2018 Registration Document filed with the AMF on February 27, 2019 under n° D.19-0078, which is available on GENFIT's website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company. In addition, even if the Company's results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

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